12/ Req for Recons

CASE OT0426[illegible]3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Joseph A. Haslwanter et al.

Application No.: 09/940,784

Filed: August 28, 2001

For: NASAL SPRAY COMPOSITIONS

Examiner: S. Tran

Group Art Unit: 1615

Bet 4-10-03

Commissioner for Patents
Washington, D.C. 20231

Sir:

REQUEST FOR RECONSIDERATION

In response to the Office Action mailed on January 31, 2003 for the subject application, applicants request reconsideration of the rejections of pending claims 15-33, in view of the following remarks.

Claims 15-17 and 21-28 were finally rejected under 35 U.S.C. § 103(a) as being rendered obvious by combination of teachings from U.S. Patent 4,728,509 to Shimizu et al., U.S. Patent 5,116,847 to Gilbert et al., and U.S. Patent 5,015,474 to Parnell. The cited documents contain the following teachings:

> The Shimizu et al. patent pertains to liquid pharmaceutical compositions for ocular or nasal application, containing a particular anti-allergic drug substance that has a very low solubility in water. To create a solution formulation, it is asserted that the formulation must contain one of polyvinylpyrrolidone, a cyclodextrin, or caffeine, as a solubilizer ingredient. Examples of the patent showing preparations that contain polyvinylpyrrolidone indicate the average molecular weights as being 40,000 or 25,000, but there is

nothing in the document that suggests using any mixture of polyvinylpyrrolidone products having different average molecular weights.

The Gilbert et al. patent is discloses compositions of the drug loperamide, including aqueous formulations that can be applied to nasal passages. Additional drug substances can be included, such as the decongestant oxymetazoline hydrochloride. However, there is no mention of any utility for certain of the ingredients required by the applicant's claims, such as polyvinylpyrrolidone.

The patent to Parnell describes moisturizing compositions that contain a natural oil, called "eriodictyon fluid." One embodiment is a liquid nasal formulation containing the decongestant ingredient ephedrine sulfate. There is no mention of polyvinylpyrrolidone in this patent.

No conceivable combination of teachings from these patents would render the applicants' claims obvious. It is not even possible to find all of the claim limitations in a combination of the teachings, and the law relating to reference combinations further requires the reference documents themselves to contain a suggestion for making the asserted combination. In M.P.E.P. § 706.02(j) the requirements for a proper rejection under 35 U.S.C. § 103 are discussed, including a statement attributed to *In re Vaeck*, 20 USPQ2d 1438 (Fed.Cir. 1991): "Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations."

This requirement likely stems from the steps for determining obviousness prescribed by the U.S. Supreme Court in *Graham v. John Deere*, 148 USPQ 459 (1966):

1. Determine the scope and contents of the prior art.
2. Ascertain the differences between the prior art and the applicants' claims.
3. Resolve the level of ordinary skill in the relevant art.

From the second step, it is apparent that differences between the claimed invention and the cited prior art would be indicative of patentability over that art.

Absent the mention in a reference of record that two or more polyvinylpyrrolidone polymers having different average molecular weights would be useful in a nasal spray

composition, there simply can be no *prima facie* case for obviousness of Claims 15-17 and 21-28, and the improper rejection of those claims should be withdrawn.

Claims 18-20 and 29-33 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over the above-discussed combination of patents, further including the teachings of E. Rybacki et al., "Auxiliary Substances in Technology of Drug Form," *Library of a Pharmacist, Volume 7*, Warsaw, 1980. The Rybacki et al. document discusses polyoxyethylene glycols, polyvinylpyrrolidone, and other substances.

However, nothing in the Rybacki et al. publication assists in overcoming the fundamental deficiency of the combined patent documents: the combination still does not include teachings of all of the limitations in the rejected claims. The legal standard discussed above applies fully to this rejection, and mandates the conclusion that the rejection is improper. This rejection should be withdrawn.

As all of the pending claims appear to be in condition for allowance, withdrawal of the rejections and an early notice of allowability are respectfully solicited. However, if any minor matters remain to be resolved for disposition of the application, please contact the undersigned to arrange for a telephonic or personal interview.

Respectfully submitted,

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